

market, especially for the rare disease community.

However, I will support this bill as it moves forward today as I believe it is important to prevent the abuse of this program in the future. I look forward to continuing discussions to come to a resolution on this outstanding concern as we work with the Senate to get this bill to the President's desk.

Madam Speaker, I reserve the balance of my time.

Mr. PALLONE. Madam Speaker, I yield such time as she may consume to the gentlewoman from Pennsylvania (Ms. DEAN), the author of this legislation, which is important because whenever we can encourage generics and make drugs more affordable, it is certainly to the benefit of the American people.

□ 1615

Ms. DEAN. Madam Speaker, I thank Representative GUTHRIE and Chairman PALLONE for their support of this critical legislation.

Madam Speaker, I rise in support of H.R. 1629, the Fairness in Orphan Drug Exclusivity Act.

This crucial legislation would close a loophole in the current law that can be used to block competition in the pharmaceutical marketplace.

The Orphan Drug Act of 1983 provided incentives for prescription drug manufacturers to develop products to treat rare diseases. This includes an exclusive 7-year marketing right for therapies that receive an orphan drug designation.

For a drug to qualify, it must either be a treatment for a disease or a condition that affects fewer than 200,000 people in the United States, or is a drug intended for diseases that there is no reasonable expectation to recoup research and development costs.

This legislation focuses on the drugs intended for diseases that there is no reasonable expectation to recoup research and development costs. It would require all drug manufacturers who obtain orphan drug status to prove that they have no reasonable expectation that they will recover their research and development costs and efforts.

This legislation works to prevent companies from continuing to use orphan drug exclusivity status for a newly approved drug, with an identical ingredient to the former version, without having to prove the inability to recoup costs.

This exact circumstance happened when a manufacturer of a buprenorphine product updated an older product that received orphan drug status and subsequently was given a renewed orphan drug exclusivity. Buprenorphine is used as a treatment for opioid use disorder to help those recovering from addiction. Unfortunately, at the time, the opioid epidemic was raging. It was, by no means, a rare disease, and the drug was not a market loser.

Closing this loophole will ensure that products do not receive an unfair mar-

ket advantage and, therefore, remains consistent with the spirit and intent of the Orphan Drug Act. We must work to ensure people can gain access to newer therapies and medically assisted treatments that are potentially blocked due to orphan designation.

Madam Speaker, I thank Representative MARC VEASEY for introducing this legislation along with me. I thank my colleagues in the House for passing this bill without objection on a voice vote just 6 months ago in the 116th Congress.

Again, I thank Chairman PALLONE for bringing this bill forward and for his leadership on substance use disorder and behavioral health issues more broadly.

Madam Speaker, I urge Members to support this bill.

Mr. GUTHRIE. Madam Speaker, I yield myself such time as I may consume for the purpose of closing.

Madam Speaker, it is so important that we have the Orphan Drug Act. We have so many people who have rare diseases come to our offices and visit us on Capitol Hill, as they should. Hopefully we will be able to do that again soon. It just touches your heart. Many of these diseases have so few people affected by it; but if it is you or your child or somebody in your family, it is devastating.

We have all seen the power of the private marketplace to come in and produce these pharmaceuticals that make a difference. So we have to have provisions to allow these drugs to come into the marketplace and incentivize that private innovation moving forward.

But when people use that in order to move forward, this loophole has to be closed. I am glad that it is here, and it is these things that we need to work on. It is really not specifically here; it is just maybe a slippery slope in other places as we move forward.

I thank my friend from Pennsylvania for bringing this forward, and the Energy and Commerce Committee for addressing this, because we have to preserve orphan drug status for those afflicted by the rarest and the most devastating diseases. We also need to bring lower drug prices to Americans, and we can do that working together.

Madam Speaker, I appreciate this being brought forward. I urge my colleagues to support this piece of legislation, and I yield back the balance of my time.

Mr. PALLONE. Madam Speaker, I yield myself such time as I may consume for the purpose of closing.

Madam Speaker, I thank Representative GUTHRIE for his remarks about trying to work together to lower the cost of prescription drugs. I thank Congresswoman DEAN because this is a part of that effort.

As you will note, today, we had a whole package dealing with mental health, behavioral health, and other drug activities. It is very important that we move this whole package and

try to get it passed in the Senate as quickly as possible.

Madam Speaker, I urge support for this legislation on a bipartisan basis, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 1629.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. GUTHRIE. Madam Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

CONTINUATION OF THE NATIONAL EMERGENCY WITH RESPECT TO YEMEN—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 117-37)

The SPEAKER pro tempore laid before the House the following message from the President of the United States; which was read and, together with the accompanying papers, referred to the Committee on Foreign Affairs and ordered to be printed:

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) provides for the automatic termination of a national emergency unless, within 90 days prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date. In accordance with this provision, I have sent to the *Federal Register* for publication the enclosed notice stating that the national emergency declared in Executive Order 13611 of May 16, 2012, with respect to Yemen is to continue in effect beyond May 16, 2021.

The actions and policies of certain former members of the Government of Yemen and others continue to threaten Yemen's peace, security, and stability. These actions include obstructing the political process in Yemen and the implementation of the agreement of November 23, 2011, between the Government of Yemen and those in opposition to it, which provided for a peaceful transition of power that meets the legitimate demands and aspirations of the Yemeni people. For this reason, I have determined that it is necessary to continue the national emergency declared in Executive Order 13611 with respect to Yemen.

JOSEPH R. BIDEN, Jr.
THE WHITE HOUSE, May 11, 2021.

CONTINUATION OF THE NATIONAL EMERGENCY WITH RESPECT TO SECURING THE INFORMATION AND COMMUNICATIONS TECHNOLOGY AND SERVICES SUPPLY CHAIN—MESSAGE FROM THE PRESIDENT OF THE UNITED STATES (H. DOC. NO. 117-38)

The SPEAKER pro tempore laid before the House the following message from the President of the United States; which was read and, together with the accompanying papers, referred to the Committee on Foreign Affairs and ordered to be printed:

To the Congress of the United States:

Section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) provides for the automatic termination of a national emergency unless, within 90 days prior to the anniversary date of its declaration, the President publishes in the *Federal Register* and transmits to the Congress a notice stating that the emergency is to continue in effect beyond the anniversary date.

In accordance with this provision, I have sent to the *Federal Register* for publication the enclosed notice stating that the national emergency declared in Executive Order 13873 of May 15, 2019, with respect to securing the information and communications technology and services supply chain, is to continue in effect beyond May 15, 2021.

The unrestricted acquisition or use in the United States of information and communications technology or services designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries augments the ability of these foreign adversaries to create and exploit vulnerabilities in information and communications technology or services, with potentially catastrophic effects. This threat continues to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. Therefore, I have determined that it is necessary to continue the national emergency declared in Executive Order 13873 with respect to securing the information and communications technology and services supply chain.

JOSEPH R. BIDEN, Jr.
THE WHITE HOUSE, May 11, 2021.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12(a) of rule I, the Chair declares the House in recess until approximately 6:30 p.m. today.

Accordingly (at 4 o'clock and 23 minutes p.m.), the House stood in recess.

□ 1830

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mrs. DINGELL) at 6 o'clock and 30 minutes p.m.

FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 1629) to amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs, and for other purposes, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill.

The vote was taken by electronic device, and there were—yeas 250, nays 168, not voting 12, as follows:

[Roll No. 134]

YEAS—250

Adams	Fitzpatrick	Mace
Aguilar	Fletcher	Malinowski
Allred	Poster	Malliotakis
Auchincloss	Frankel, Lois	Maloney,
Axne	Gallego	Carolyn B.
Barragán	Garamendi	Maloney, Sean
Bass	Garbarino	Manning
Beatty	Garcia (CA)	Massie
Bera	Garcia (IL)	Matsui
Beyer	Garcia (TX)	McBath
Bishop (GA)	Gomez	McCaul
Blumenauer	Gonzales, Tony	McClintock
Blunt Rochester	Gonzalez (OH)	McCollum
Bonamici	Gonzalez,	McEachin
Bost	Vicente	McGovern
Bourdeaux	Gottheimer	McNerney
Bowman	Green, Al (TX)	Meeks
Boyle, Brendan	Grijalva	Meijer
F.	Harder (CA)	Meng
Brown	Hartzler	Mfume
Brownley	Hayes	Moore (WI)
Burchett	Herrera Beutler	Morelle
Bush	Higgins (NY)	Moulton
Bustos	Himes	Mrvan
Carbajal	Hollingsworth	Murphy (FL)
Cárdenas	Horsford	Nadler
Carson	Houlahan	Napolitano
Carter (LA)	Hoyer	Neguse
Cartwright	Huffman	Newhouse
Case	Jackson Lee	Newman
Casten	Jacobs (CA)	Noircross
Castor (FL)	Jacobs (NY)	O'Halleran
Castro (TX)	Jayapal	Ocasio-Cortez
Cawthorn	Jeffries	Omar
Chu	Johnson (GA)	Pallone
Cicilline	Johnson (SD)	Panetta
Clark (MA)	Johnson (TX)	Pappas
Clarke (NY)	Jones	Pascarella
Cleaver	Kahele	Payne
Clyburn	Kaptur	Perlmutter
Cohen	Katko	Peters
Connolly	Keating	Phillips
Cooper	Kelly (IL)	Pingree
Correa	Khanna	Pocan
Costa	Kildee	Porter
Courtney	Kilmer	Pressley
Craig	Kim (CA)	Price (NC)
Crist	Kim (NJ)	Quigley
Crow	Kind	Raskin
Cuellar	Kinzinger	Rice (NY)
Davids (KS)	Kirkpatrick	Ross
Davidson	Krishnamoorthi	Roybal-Allard
Davis, Danny K.	Kuster	Ruiz
Dean	Lamb	Ruppersberger
DeGette	Langevin	Rush
DeLauro	Larsen (WA)	Ryan
DelBene	Larson (CT)	Salazar
Delgado	Lawrence	Sánchez
Demings	Lawson (FL)	Sarbanes
DeSaulnier	Lee (CA)	Scanlon
Deutch	Lee (NV)	Schakowsky
Dingell	Leger Fernandez	Schiff
Doggett	Levin (CA)	Schneider
Doyle, Michael	Levin (MI)	Schrader
F.	Lieu	Schrier
Escobar	Lofgren	Scott (VA)
Eshoo	Lowenthal	Scott, David
Españolat	Luria	Sewell
Evans	Lynch	Sherman

Sherrill	Taylor	Vargas
Sires	Tenney	Veasey
Slotkin	Thompson (CA)	Vela
Smith (NJ)	Thompson (MS)	Velázquez
Smith (WA)	Titus	Wagner
Soto	Tlaib	Walorski
Spanberger	Tonko	Wasserman
Speier	Torres (CA)	Schultz
Stanton	Torres (NY)	Waters
Steel	Trahan	Watson Coleman
Stevens	Trone	Welch
Stivers	Underwood	Wexton
Strickland	Upton	Wild
Suozzi	Valadao	Williams (GA)
Swalwell	Van Drew	Wilson (FL)
Takano	Van Duyne	Yarmuth

NAYS—168

Aderholt	Gallagher	Miller (WV)
Allen	Gibbs	Miller-Meeks
Amodei	Gimenez	Moolenaar
Armstrong	Gohmert	Mooney
Arrington	Good (VA)	Moore (UT)
Babin	Gooden (TX)	Mullin
Bacon	Gosar	Murphy (NC)
Baird	Granger	Nehls
Balderson	Graves (LA)	Norman
Banks	Graves (MO)	Nunes
Barr	Green (TN)	Oberholte
Bentz	Greene (GA)	Palazzo
Bergman	Griffith	Palmer
Bice (OK)	Grothman	Pence
Biggs	Guest	Perry
Bilirakis	Guthrie	Pfluger
Bishop (NC)	Hagedorn	Posey
Boebert	Harris	Reed
Brady	Harshbarger	Reschenthaler
Brooks	Hern	Rice (SC)
Buchanan	Herrell	Rodgers (WA)
Buck	Hice (GA)	Rogers (AL)
Bucshon	Higgins (LA)	Rogers (KY)
Budd	Hill	Rose
Calvert	Hinson	Rosendale
Cammack	Hudson	Rouzer
Carl	Huizenga	Roy
Carter (GA)	Issa	Rutherford
Carter (TX)	Jackson	Scalise
Chabot	Johnson (LA)	Schweikert
Cheney	Johnson (OH)	Scott, Austin
Cline	Jordan	Simpson
Cloud	Joyce (OH)	Smith (MO)
Clyde	Joyce (PA)	Smith (NE)
Cole	Keller	Smucker
Comer	Kelly (MS)	Spartz
Crawford	Kelly (PA)	Stauber
Crenshaw	Kustoff	Stefanik
Curtis	LaHood	Steil
DesJarlais	LaMalfa	Steube
Diaz-Balart	Lamborn	Stewart
Donalds	Latta	Tiffany
Duncan	LaTurner	Timmons
Emmer	Lesko	Turner
Estes	Letlow	Walberg
Fallon	Long	Waltz
Feenstra	Loudermilk	Weber (TX)
Ferguson	Lucas	Wenstrup
Fischbach	Luetkemeyer	Westerman
Fitzgerald	Mann	Williams (TX)
Fleischmann	Mast	Wilson (SC)
Fortenberry	McCarthy	Wittman
Fox	McClain	Womack
Franklin, C.	McHenry	Young
Scott	McKinley	Zeldin
Fulcher	Meuser	
Gaetz	Miller (IL)	

NOT VOTING—12

Burgess	Dunn	Owens
Butterfield	Golden	Sessions
Davis, Rodney	Moore (AL)	Thompson (PA)
DeFazio	Neal	Webster (FL)

□ 1905

Messrs. STEWART, GALLAGHER, Ms. LETLOW, and Mr. GROTHMAN changed their vote from “yea” to “nay.”

Mses. MACE and TENNEY changed their vote from “nay” to “yea.”

So (two-thirds not being in the affirmative) the motion was rejected.

The result of the vote was announced as above recorded.